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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,194	10/31/2001	Reto Schoeb	015258-048710US	6423

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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	5

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,194	SCHOEB, RETO	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2001 (Preliminary amendment)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11,.453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☒ Claim(s) *27-29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in the EPO on 18 Aug. 2000. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

Claim Objections

2. Claims 27-29 are objected to because of the following informalities: Claims 27-29 recite a bioreactor while the claims depend from method claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5, 6 and 17-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5, while the claim recites a downward flow of fluid, it is not clear in view of the recited limitations how this can be achieved in the absence of further positively recited structure of the bioreactor.

In claim 17, it is not clear what is intended by the claim limitation "has at least one closable opening above". Above what?

In claim 20, "the fluid conveying apparatus" lacks antecedent basis. Note claim 20 depends from claim 7 not claim 8.

In claim 21, "the fluid conveying apparatus" lacks antecedent basis. Note claim 21 depends from claim 7 not claim 8.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 7, 9-11 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Starkie et al. (WO 86/00636).

The reference of Starkie et al. discloses a device and method of use which provides a first flow chamber to which a fluid is supplied such that the fluid flowing upwardly therein has a lower speed with increasing height (See Figures 1, 2 and 5).

7. Claims 1, 2, 5-7, 9-14, 16, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Dean, Jr. et al.(US 4,978,616).

The reference of Dean, Jr. et al. discloses device and method of use which includes a chamber (12); flow guiding means (14) which is positioned in the chamber so as to provide the required decreased flow with height; fluid conveying device (10) which includes an external

motor and internal fluid conveying means (22-28). The device also includes oxygenation system (130) which introduces oxygen into a downward flow of fluid and introduced the gaseous media into the liquid media such that it is introduced with the upward flow of media into the flow chamber.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 17-19 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean, Jr. et al. (US 4,978,616).

The reference of Dean, Jr. et al. has been discussed above.

With respect to the claimed sealable opening, while the reference is silent to this opening, it would have been obvious to one of ordinary skill in the art to provide the top of the reactor of

Dean, Jr. et al. with an access opening for the known and expected result of providing a means recognized in the art for cleaning and/or otherwise accessing the interior of the reactor without the need to disassemble the entire device.

With respect to the specifics of the impeller motor and blade, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum manner in which to pump the fluid based on considerations such as the size of the reactor and properties of the media to be employed.

11. Claims 4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Dean, Jr. et al.(US 4,978,616) or Starkie et al.(WO86/00636) taken in view of Reh et al.(US 5,538,162).

The references of Dean, Jr. et al. and Starkie et al. have been discussed above.

The above claims differ by reciting that the system includes a sensor and controller for controlling the flow of fluid in response to a position of the substance that is acted on by the flow of fluid.

The reference of Reh et al. discloses that it is known in the art to employ level sensors in the fluidized bed so as to control mass flow in the system (See sensors 15 and 12 in Figure 7 and claim 1).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the primary references with level sensors for the known and expected result of controlling the height of the fluidized material by controlling the flow of fluid in response to the detected height or level of the fluidized bed of material in the fluid flow zone.

Allowable Subject Matter

12. Claims 15 and 27-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claim 15, while the prior art of record discloses a device for defining a flow chamber within a bioreactor device using a hollow body as a flow guiding means, the prior art of record fails to teach or fairly suggest defining a flow chamber between the container wall of the reactor and the outer contour of a hollow body which includes an upwardly reducing outer contour (See Figure 2b of the instant application).

With respect to claims 27-29, the prior art of record fails to teach or fairly suggest a bioreactor device that includes a first chamber and second chamber above the first chamber such that a fluid entering the bottom of the first chamber flowing upwardly has a lower speed with increasing height and a fluid entering the top of the second chamber flowing downwardly has a lower speed with respect to its distance from the top inlet.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-75 of copending Application No. 09/655,203. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are anticipated by claims 38-75 of Application 09/655,203. Claims 38-75 differ because they positively recite the use of tissue scaffolding as part of the claimed device and method of use.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following references are cited of interest because they were cited in parent application 09/655,203:

Schoeb et al.(US 6,100,618) ; Freedman et al.(US 5,501,971); Gilwood (US 5,445,073); Knaack et al.(US 5,320,963) and Scholler et al.(US 2,083,348).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

William H. Beisner
Primary Examiner
Art Unit 1744

WHB